



Global Overview of the Threat

*U.S. Drug Enforcement Administration / Operations
Division / Office of Diversion Control*



A global problem
that constitutes a
significant public
health threat
to many nations !!!



United Nations Office on Drugs and Crime

The challenge of
new psychoactive substances

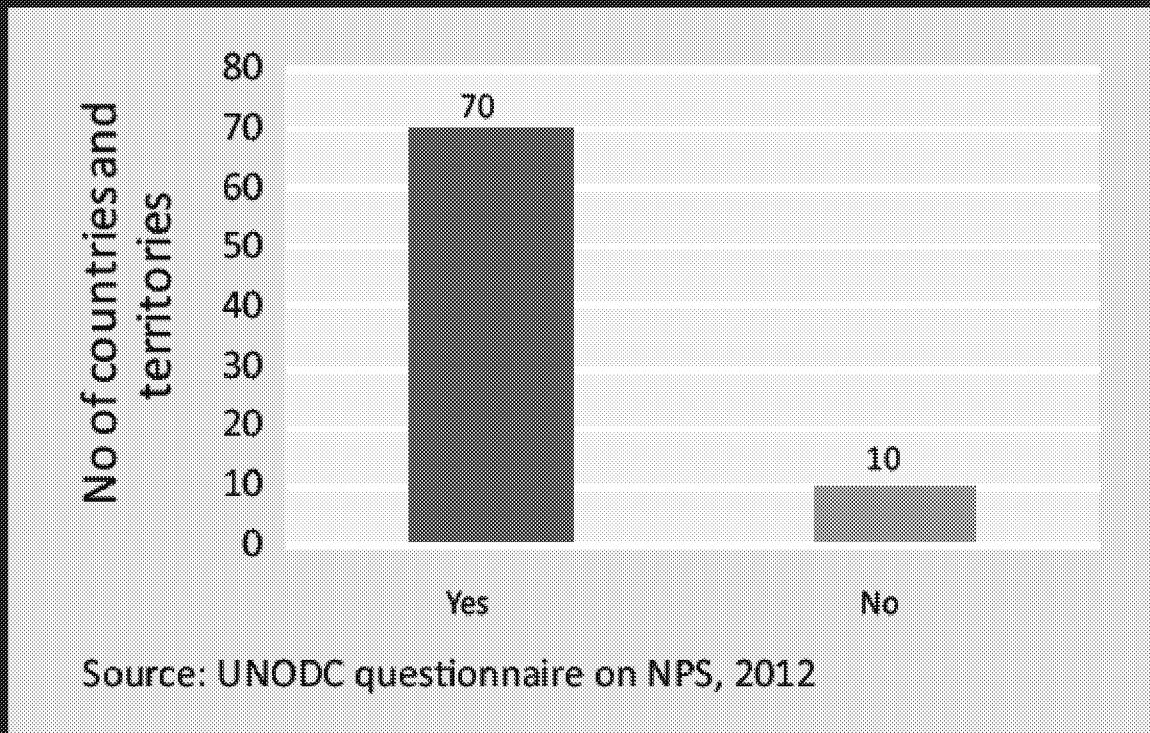


Global SMART Programme

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Global Synthetic Drug Use



Of the nations surveyed, 87 % (70 out of 80) indicate that NPS are available in their respective drug markets.



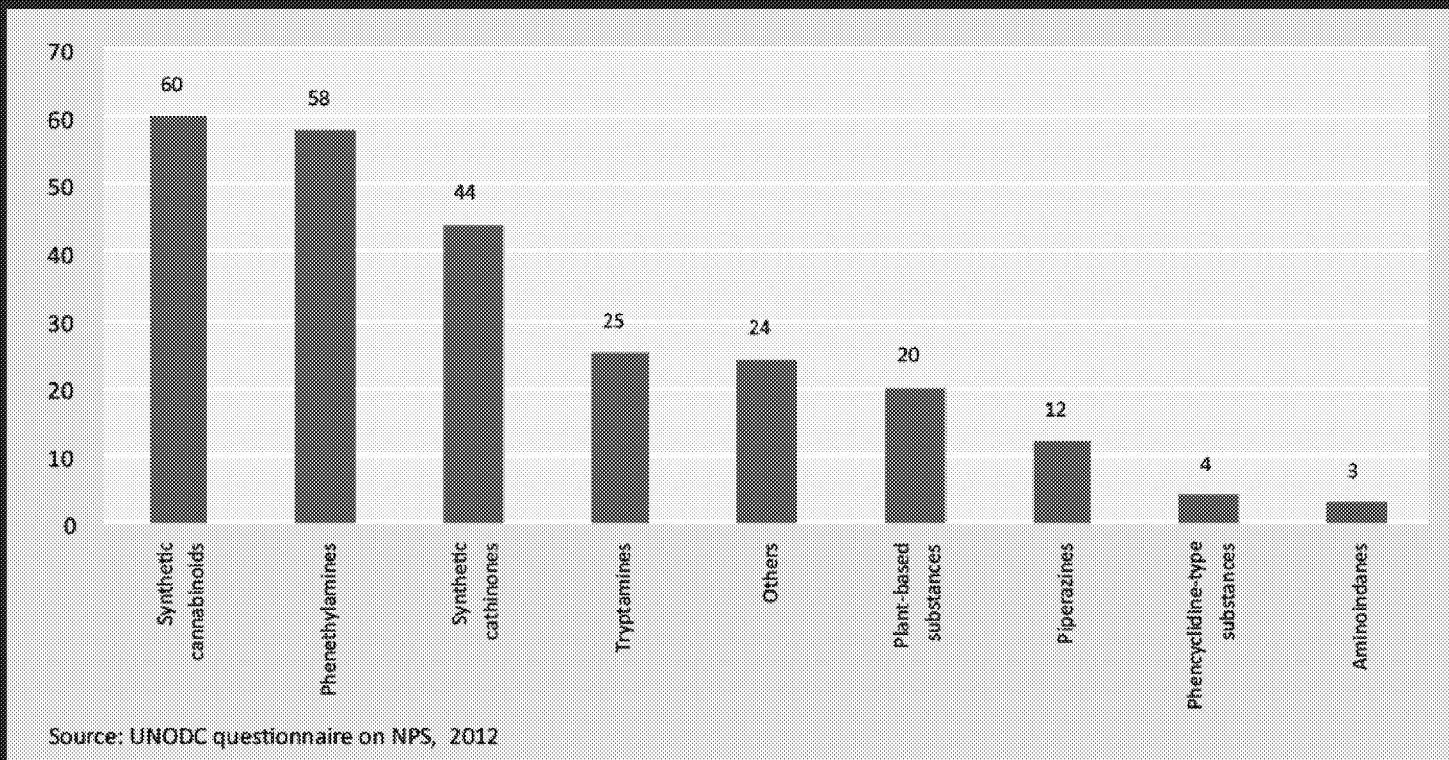
Global Synthetic Drug Use



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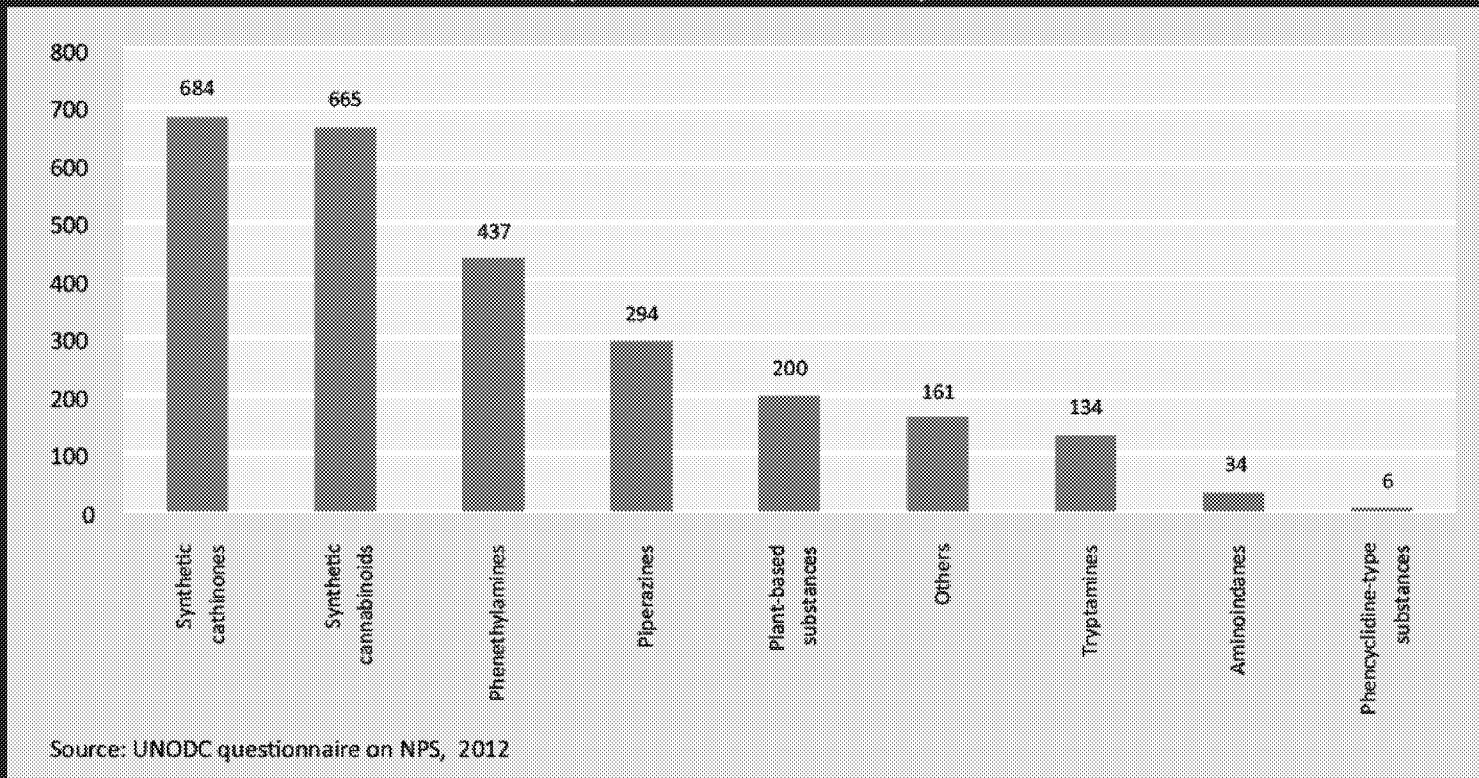
Number of NPS on Global Markets (2009-2012)



A total of 251 NPS (including ketamine) were reported to UNODC by 40 countries and territories up to 2012.



Number of NPS in Global Markets (2009-2012)



At the global level, most reports pertaining to NPS concern synthetic cathinones, with 684 reports, followed by synthetic cannabinoids with 665 reports



Trend of NPS Seizures (2009 – 2012)

NPS group	2009	2010	2011	2012
Synthetic cannabinoids	↑	↑	↑	↑
Synthetic cathinones	↑	↑	↑	↔
Ketamine	↔	↔	↔	↔
Phenethylamines	↔	↑	↔	↔
Piperazines	↑	↔	↔	↓
Plant-based substances	↑	↑	↑	↔
Miscellaneous	-	↑	↑	↑

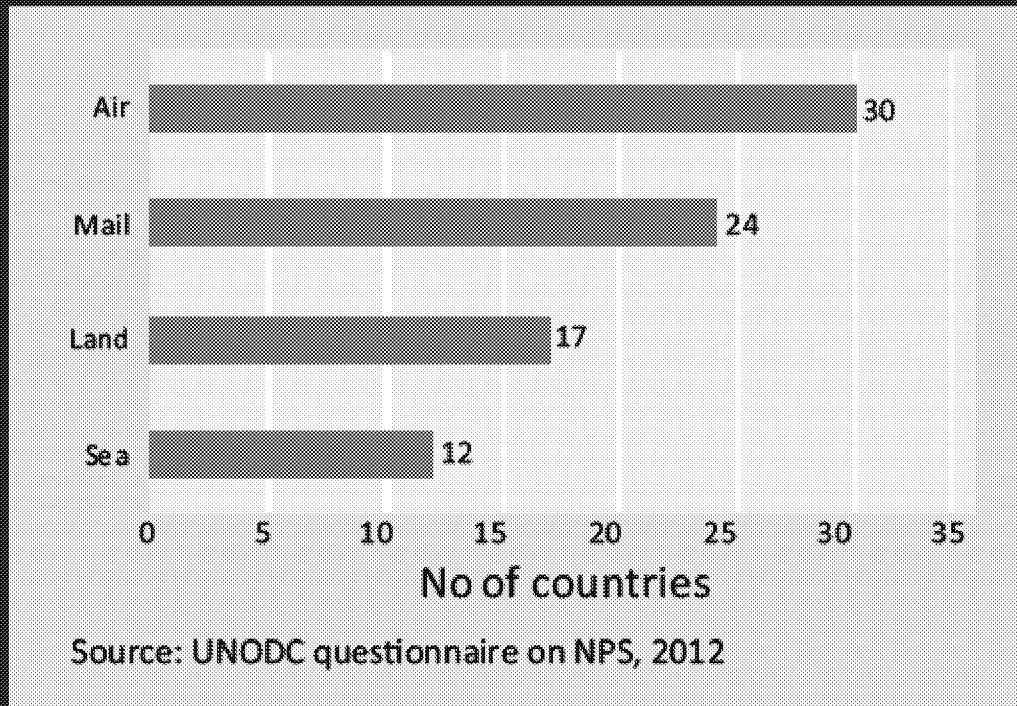
↑ = Increasing, ↓ = Decreasing, ↔ = Stable, - unknown

Source: UNODC questionnaire on NPS, 2012 and ARQ

Trends for the seven NPS groups fluctuate.
 Seizures of ketamine, phenethylamines and piperazines stable
 Rising trends for synthetic cannabinoids, cathinones,
 and plant-based substances



NPS Trafficking Modes



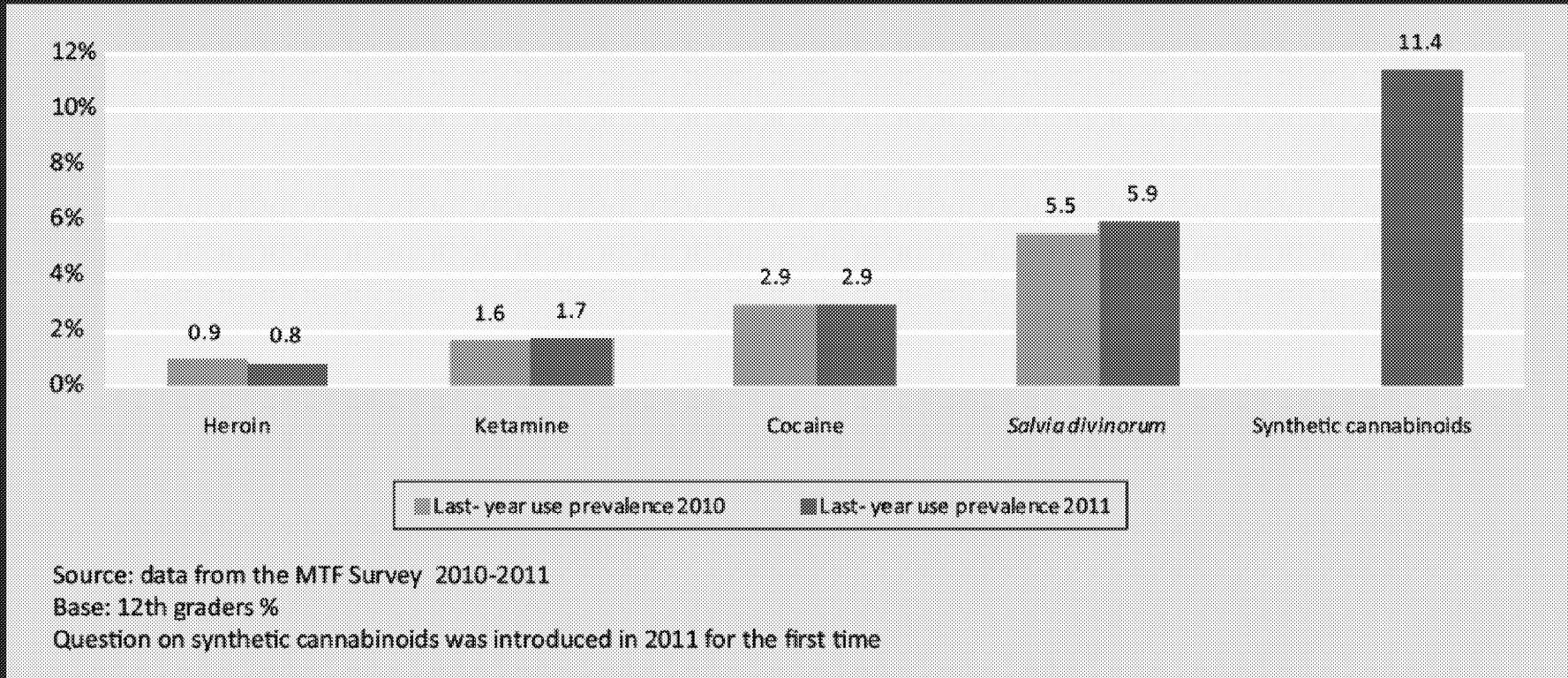
The mode of trafficking named by most respondents was trafficking by air (30 countries) followed by trafficking by mail (24 countries), without any regional variations.



U. S. Overview & Experience

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United States: Prevalence of Drug and NPS Use Among 12th Graders (2010 – 2011)





Identified Synthetic Compounds in the U.S.

As of October 15, 2013, the U.S. has encountered:

- 99 synthetic cannabinoids
- 52 synthetic cathinones
- 89 other compounds (2C compounds, tryptamines, piperazines, etc.)

240 Compounds and Counting !!!!



'Spice' makers alter recipes to sidestep state laws banning synthetic marijuana



Rob Ostermaier/Daily Press - Police show what they suspect is "spice," confiscated during a raid on Outer Edge Gifts in Hampton, Va., on April 5.

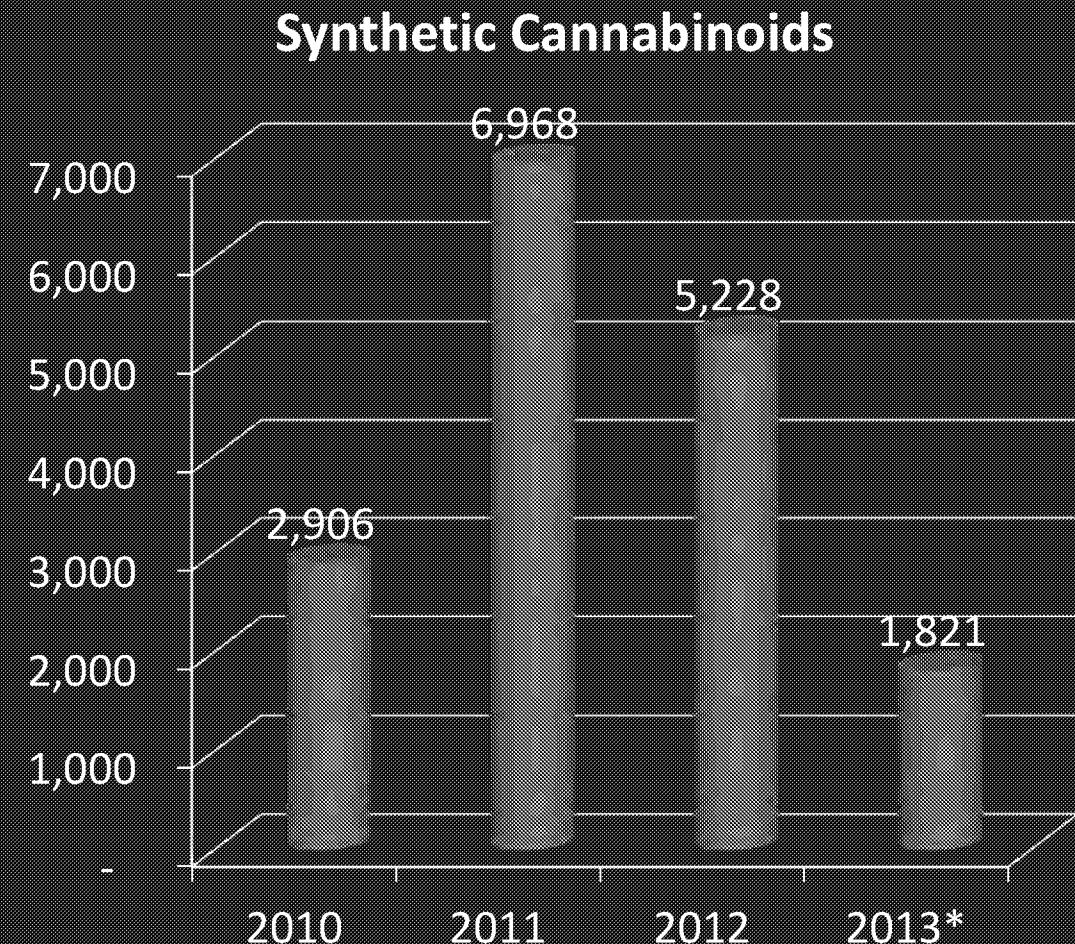
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Calls to U.S. Poison Control Centers

American Association of
Poison Control Centers
(AAPCC) Reporting

Calls to poison control
centers for exposures to
synthetic marijuana
(synthetic cannabinoids)



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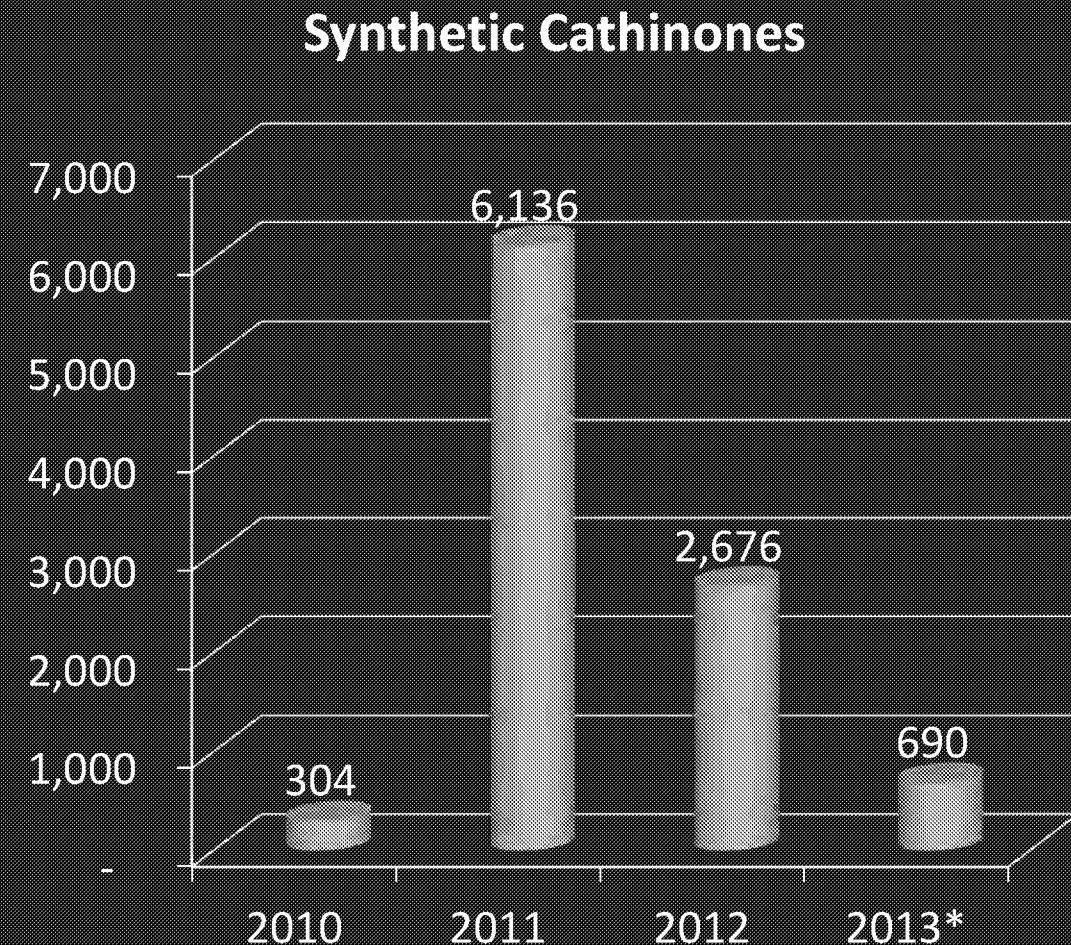
*As of August 31, 2013



Calls to U.S. Poison Control Centers

American Association of
Poison Control Centers
(AAPCC) Reporting

Calls to poison control
centers for exposures to
bath salts (synthetic
cathinones)



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*As of August 31, 2013



Public Safety Concerns

- Driving Under the Influence of Drugs (DUIDs) with fatalities
- Suicides
- Homicide-Suicide
- Overdoses
 - Emergency Department visits
 - First Responders
- Drugs abused to evade drug screens
 - 30-35% of juveniles in drug court tested positive
 - Individuals subjected to routine drug screens
 - Probationer / parolees



Warning!

Bangor Daily News

Bangor man on bath salts carried assault-style rifle through city, police say

By Nok-Noi Ricker, BDN Staff

Posted July 27, 2011, at 12:50 p.m.

the man's ex-girlfriend told police at about 7:30 p.m. Tuesday that he had used bath salts and was "stating that people were coming out of his mattress,"

when Bangor police officers responded to a call at a Walter Street apartment around 7:30 p.m. Tuesday. Police searched the apartment and found an M4 assault-style rifle and two pieces wrapped in plastic containing .223 [caliber] ammunition. "When questioned, the man stated that he had used bath salts and was stating that people were coming out of his mattress,"

He did not tell police where he obtained the gun.

A local agent of the Drug Enforcement Administration interviewed the suspect.

The man was released Tuesday evening. The case is being reviewed for possible state and/or federal charges, Edwards said.



, went into the man's

orn found the man on Buck

I did in fact find an M4 rifle in
e and 18 separate rounds of

said, adding, "we did confiscate

ng with Bangor police,



First Responder Encounters

- Altered mental status presents as severe panic attacks, agitation, paranoia, hallucinations, and violent behavior (e.g., self-mutilation, suicide attempts, and homicidal activity). (Spiller *et al.*, *Clinical Toxicology* 2011)
 - climbing into the attic of the home with a gun to kill demons that were hiding
 - breaking all the windows in a house and wandering barefoot through the broken glass
 - jumping out of a window to flee from non-existent pursuers; requiring electrical shock (Taser) and eight responders to initially subdue the patient
 - repeatedly firing guns out of the house windows at “strangers” who were not there
- Bath salts use tied to three Bangor (Maine) deaths. (Richter, *JEMS* 2012)
- Bath salt abuse: new designer drug keeps EMS crews busy nationwide. (Nevin, *JEMS* 2011)



First Responders (Cont.)

Drug Endangered Children:

- Leaving a child unattended in the middle of a highway because she had demons (Spiller *et al.*, *Clinical Toxicology* 2011)
- A drug-intoxicated couple hallucinated they were being burglarized, began shooting into walls. Officers found weapons in every room, and a paranoid parent huddled inside the bathroom with a handgun and a loaded .357 Magnum (Macher, *American Jails* 2011)
- Northeast PA, couple charged with multiple offenses for stabbing at “90-people living in their walls” with kitchen knives (Times-Leader.com, Mar 21, 2011)



Synthetic Drug “Manufacturing Facility”?



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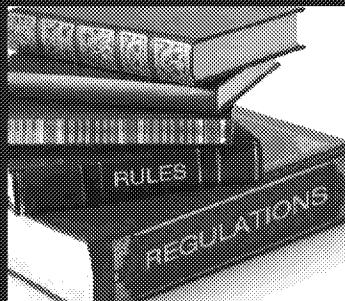


U.S. Drug Enforcement Administration - Operations
Division of Office of Diversion Control



Ready to Ship...





Control Efforts: Using all the “Tools” Available



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Synthetic Drugs: U.S. State Controls

- Legislation
- Department of Health
- Pharmacy Board
- Consumer Affairs Dept.



U.S. Federal Scheduling & Rescheduling Procedures

Placement of a substance into one of the U.S. Federal Controlled Substance Act (CSA) schedules can be done by statute or through the administrative process.

- **Statute:** Congress may designate a substance a controlled substance or reschedule a drug within the scheduling hierarchy by passing legislation. This, by far, is the easiest method in which to add, remove or transfer a substance between schedules.

- **Administrative Process:** The Attorney General, by rule, (using his administrative authority) to add, remove or transfer a substance between schedules. **The legal definition of control, “...means to add a drug or other substance, or immediate precursor, to a schedule...whether by transfer of another schedule or otherwise”.** 21 USC 802(5)



Federal Temporary Scheduling

- Because of the lack of effective legislative controls to combat the synthetic problem early on, federally we looked to temporary scheduling as a solution
- Requires an AG finding (delegated down to DEA) that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety
- ...and the substance is not listed in any other schedule in Section 21 USC 812 or no exemption or approval is in effect under the FDCA



Federal Temporary Scheduling (Comprehensive Crime Control Act of 1984)

As set forth under 21 U.S.C 811(h), three factors (4, 5 &6) under the CSA (21 U.S.C. 811(c)) are to be considered in the evaluation

1. Its actual or relative potential for abuse
2. Scientific evidence of its pharmacological effects
3. The state of current scientific knowledge regarding the substance
4. Its history and current pattern of abuse
5. The scope, duration, and significance of abuse
6. What, if any, risk there is to the public health
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled



Federal Temporary Scheduling Process

- DEA collects information from law enforcement and public health officials regarding encounters and evaluates this information relative to the three factors required for temporary scheduling.
- Once sufficient information has been collected, a letter is transmitted from DEA to the U.S. Department of Health & Human Services (DHHS) to communicate intention to temporary schedule [and to verify no active new drug applications (NDAs) or investigations drug applications (INDs) for the proposed substances filed].



Federal Temporary Scheduling Process

- DEA letter of intent to DHHS, solicits a comment to control these substances within 30 days. Based on the DHHS response, a “Notice of Intent” can be published in the U.S. Federal Register with a “Final Order” published at minimum 30-days after the “Notice of Intent”.

- As there is no “comment period” provided for temporary scheduling, civil and criminal sanctions applicable to the manufacture, possession, importation, and exportation are effective upon publication of the “Final Order”.



U.S. Federal Temporary Scheduling Actions to Date Relative to Synthetic Drugs

21858 *Federal Register / Vol. 78, No. 71 / Friday, April 12, 2013 / Proposed Rules*

Published in Washington, DC, on April 4, 2013.

Gary A. Nardino,
Associate, Agency Policy and ALC
Proceedings Division,
500 I St., NW, Office of Legal, 600-33-10, 600-33-2
861-1902, 202-501-4966-33-2

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1308
(Docket No. DEA-073)

Schedules of Controlled Substances:
Temporary Placement of Three
Synthetic Cannabinoids into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of Intent.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is placing this series of intent to temporarily reclassify three synthetic cannabinoids into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(d)(2). The substances are 1-penty-1-(3-(2,2,3,3-tetramethylcyclopropyl)indole) (UR-144), 1-(5-fluoro-penty)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; K1R11) and N-(1-adamantyl)-1-penty-1H-indazole-3-carboxamide (APINACA; AKB48).

The authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b)(1) if he finds that such action is necessary to avoid imminent danger to the public safety, 21 U.S.C. 811(d)(2). If these requirements are satisfied under 21 U.S.C. 811(d)(2), the Attorney General may extend the temporary scheduling up to one year.

When the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule or if it has been previously designated or appears in effect under section 503 of the Federal Food, Drug, and Cosmetic Act (FFDA) and 21 U.S.C. 350a for the substance. The Attorney General has determined his authority under 21 U.S.C. 811 to the best of his knowledge, based on the information he has available in the Drug Administration of DEA, or 21 CFR 1308, Appendix to Subpart K.

Section 811(d)(2) of the CSA (21 U.S.C. 811(d)(2)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of any temporary placement of substances into Schedule I of the CSA. The Deputy Administrator has undertaken notice of its intent to place UR-144, K1R11, and AKB48 in Schedule I on a temporary basis to the Assistant Secretary by letter dated February 4, 2013. The Assistant Secretary has informed the Deputy Administrator that he has received the letter dated March 4, 2013, prepared by HHS on March 1, 2013, and advised that before its review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for either UR-144, K1R11, and AKB48 in Schedule I on a temporary basis to the Assistant Secretary by letter dated February 4, 2013. The Assistant Secretary has informed the Deputy Administrator that FDA has no objection to the temporary placement of UR-144, K1R11, and AKB48 into Schedule I of the CSA. FDA has taken into consideration the Assistant Secretary's comments. As UR-144, K1R11, and AKB48 are not currently listed in any schedules under the CSA, as to its classification or reclassification, see 21 CFR 1308.

FOR FURTHER INFORMATION CONTACT: Gary W. Partington, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, Mailbox Address 12-200, 500 I Street, NW, Washington, DC 20537, telephone (202) 501-3746.

SUPPLEMENTARY INFORMATION:

Background:

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with

the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b)(1) if he finds that such action is necessary to avoid imminent danger to the public safety, 21 U.S.C. 811(d)(2). If these requirements are satisfied under 21 U.S.C. 811(d)(2), the Attorney General may extend the temporary scheduling up to one year.

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Conclusion: The Secretary of the Department of Health and Human Services (HHS) has developed in the Assistant Secretary for Health the Department of Health and Human Services (DHHS) policy concerning the classification of synthetic cannabinoids into Schedule I of the CSA. This policy is intended to implement the recommendations of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) regarding the classification of synthetic cannabinoids. These synthetic cannabinoids, of which 1-penty-1H-indazole-3-carboxamide (UR-144), 1-(5-fluoro-penty)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; K1R11) and N-(1-adamantyl)-1-penty-1H-indazole-3-carboxamide (APINACA; AKB48) are representative are so formulated for their psychoactive characteristics that they have been approved by FDA for human consumption. These synthetic cannabinoids (Figure 1) and are pharmaceutically similar to the Schedule I hallucinogen delta-9-tetrahydrocannabinol (Δ^9 -THC). UR-144 was first developed as a research tool by Abbott laboratories (Frost et al., 2010). K1R11 and AKB48 were not designed as research tools, however began showing up in seizures as early as 2009, from January 2009 through April 30, 2013 according to the System to Retrieve Information on Drug

1-penty-1-(3-(2,2,3,3-tetramethylcyclopropyl)indole) (UR-144),
1-(5-fluoro-penty)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; K1R11) and N-(1-adamantyl)-1-penty-1H-indazole-3-carboxamide (APINACA; AKB48)

Background Information and Evaluation of 'Three Factor Analysis' (Factors 4, 5 and 6) for Temporary Scheduling

Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537

April 10, 2013

Introduction

Since 2009, there has been a marked increase in the law enforcement encounters of various synthetic cannabinoids in the United States. Both law enforcement and public health reports suggest the sustained popularity of these substances in the designer drug market, most commonly abused as plant material adulterants. These associated products are often being sold as incense and labeled 'not for human consumption'. Additionally, these products are marketed as a 'legal high' or 'legal alternative to marijuana' and are readily available over the internet, in head shops, or sold in convenience stores.

These substances have no accepted medical use in the United States and have been reported to produce adverse effects in humans. Chronic abuse of synthetic cannabinoids in general has been linked to adverse health effects including signs of addiction and withdrawal (Zimmermann et al., 2009; Muller et al., 2010), as well as numerous reports of emergency room admissions resulting from their abuse (Forrester et al., 2011; Hermaann-Olauzen et al., 2012; SAMHSA, 2010).

1-penty-1-(3-(2,2,3,3-tetramethylcyclopropyl)indole) (UR-144), 1-(5-fluoro-penty)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; K1R11) and N-(1-adamantyl)-1-penty-1H-indazole-3-carboxamide (APINACA; AKB48) are synthetic cannabinoids (Figure 1) and are pharmaceutically similar to the Schedule I hallucinogen delta-9-tetrahydrocannabinol (Δ^9 -THC). UR-144 was first developed as a research tool by Abbott laboratories (Frost et al., 2010). K1R11 and AKB48 were not designed as research tools, however began showing up in seizures as early as 2009, from January 2009 through April 30, 2013 according to the System to Retrieve Information on Drug

DEA/DOJ/ODE page 1 of 19 Apr. 10, 2013



U.S. Federal Temporary Scheduling Actions Relative to Synthetic Drugs

To date, 8 Synthetic Cannabinoids, 3 Synthetic Cathinone, and 3 Phenethylamine Compounds have been controlled or in the process of being controlled

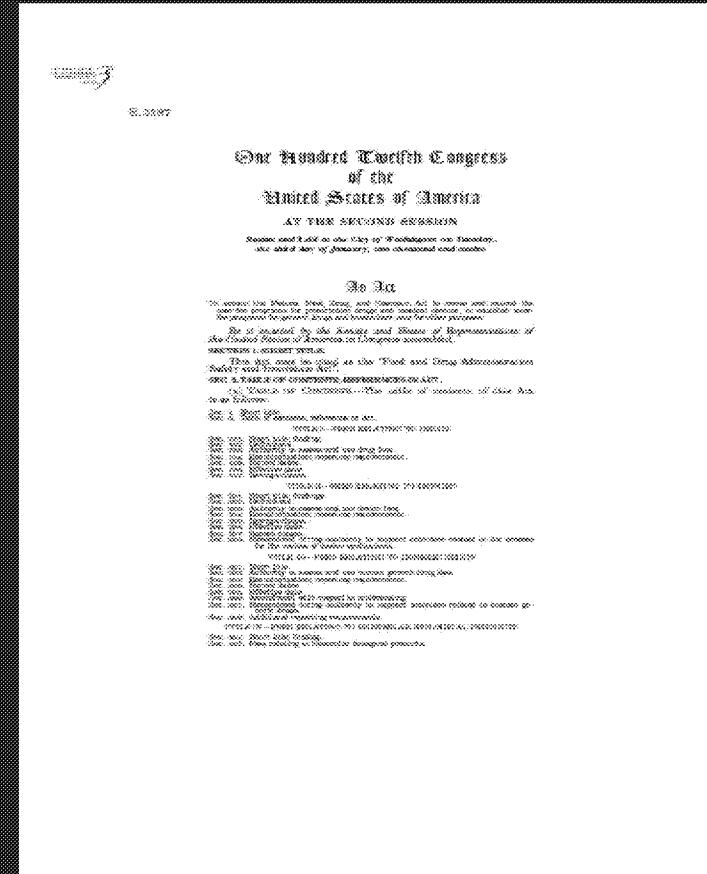
- 5 Cannabinoid Compounds (March 2011 Final Order)
- 3 Cathinone Compounds (October 2011 Final Order)
- 3 Cannabinoid Compounds (May 2013 Final Order)
- 3 Phenethylamine Compounds [i.e. “NBOMe” products (October 2013 Notice of Intent)]



U.S. Synthetic Drug Abuse Prevention Act of 2012

On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144)

- The law controlled 26 compounds into schedule I





U.S. Synthetic Drug Abuse Prevention Act of 2012

- Defined the term “Cannabimimetic Agent” [any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist].
- Extends the maximum time that DEA may temporarily control a substance.
- Initial time period for temporary scheduling increased from 12 to 24 months / Extension period increased from 6 months to 12 months.



U.S. Synthetic Drug Abuse and Prevention Act 2012

Cannabinoids

- 1) AM2201
- 2) AM694
- 3) CP-47,497
- 4) CP-47,497 –
C8 homologue
- 5) JWH-018
- 6) JWH-073
- 7) JWH-081
- 8) JWH-200
- 9) JWH-019
- 10) JWH-250
- 11) JWH-122
- 12) JWH-203
- 13) JWH-398
- 14) SR-19
- 15) SR-18

Cathinones

- 1) Mephedrone
- 2) MDPV

Phenethylamines

- 1) 2C-E
- 2) 2C-D
- 3) 2C-C
- 4) 2C-I
- 5) 2C-T-2
- 6) 2C-T-4
- 7) 2C-H
- 8) 2C-N
- 9) 2C-P



The Way Forward on the International Front

- Working to identify major foreign based sources
- Working to sensitize partner nations regarding the threat and the need for international controls
- Continue to work bilaterally and with international partners to look at coordinating global outreach and cooperation



The Way Forward on the International Front / CND Resolutions

Enhancing International Cooperation in the Identification & Reporting of NPS (E/CN.7/2013/L.2/ March 2013)

United Nations

E/CN.7/2013/L.2/Rev.1



Economic and Social Council

Distr. Limited
14 March 2013

Original: English

Commission on Narcotic Drugs

Fifty-sixth session
Vienna, 11-15 March 2013
Agenda item 4
Implementation of the international drug control treaties

Australia, Croatia, El Salvador, Finland, Hungary, Israel, Japan, Mexico,
New Zealand, Paraguay, Russian Federation, Thailand, Turkey, Ukraine,
United Kingdom of Great Britain and Northern Ireland and
United States of America: revised draft resolution

Enhancing international cooperation in the identification and reporting of new psychoactive substances

The Commission on Narcotic Drugs,

Recalling its resolution 53/1 of 11 March 2010, on promoting the sharing of information on emerging trends in the abuse of and trafficking in substances not controlled under the international drug control conventions;

Recalling also its resolution 53/11 of 11 March 2010, on promoting the sharing of information on the potential abuse of and trafficking in synthetic cannabinoid receptor agonists;

Recalling further its resolution 53/13 of 11 March 2010 on the use of "poppers" as an emerging trend in drug abuse in some regions;

Recalling its resolution 55/1 of 16 March 2012, on promoting international cooperation in responding to the challenges posed by new psychoactive substances;

Reiterating its concern at the number of potentially dangerous new psychoactive substances that continue to be marketed as legal alternatives to internationally controlled drugs, circumventing existing controls;

Concerned that emerging new psychoactive substances may have effects similar to those of internationally controlled drugs and may pose risks to public health and safety, and noting the need for additional data on the effects of these substances to be collected and shared;

V.13.51832 (E)





The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution:

- *Encourages* nations to take a comprehensive and coordinated approach to the detection, analysis, and identification of NPS
- *Urges* nations to share with one another information on the identification of NPS using, where appropriate, existing national and regional early warning systems and networks
- *Urges* nations to include information on the potential adverse impacts and risks to public health and safety of new psychoactive substances through prevention & awareness to counter public perceptions on NPS



The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution (Continued):

- *Encourages* nations, and relevant international institutions, to share and exchange ideas, best practices, and experiences regarding new laws, regulations and restrictions, to attack the NPS issue

- *Urges* the UNODC to continue to develop a voluntary electronic portal for national forensic and/or drug testing laboratories to enable timely and comprehensive sharing of information on NPS (an early warning system)



Thank You

*U.S. Drug Enforcement Administration / Operations
Division / Office of Diversion Control*